

## REMARKS

Amendments to the claims have been made to respond to the issues and concerns raised in the Office Action, to clarify aspects in the specification and claims, and to refine claim language. The amendments are believed to be consistent with the disclosure originally filed. The amendments also have been particularly presented to avoid, where applicable, any admission or estoppel, generally, negatively affecting the scope of protection provided by the disclosure and claims of the present application, and also in a manner that avoids prosecution history estoppel, limitation of the scope of equivalences, or the like. Any amendment should not be construed as an admission regarding the propriety of any objection or rejection raised in any Office Action, and the Applicant reserves the right to pursue the full scope of the unamended claims in any subsequent patent application as may be appropriate.

In this response, claim 138 has been amended. Claims 1-137 have been cancelled. Claims 138-145 remain in the application. Each amendment is believed to have been made in accordance with 37 C.F.R. § 1.121. However, should any unintended informality exist, it is requested that the undersigned be contacted by telephone so that it may be resolved as expeditiously as possible. It is believed the amendments fully respond to the issues raised in the Office Action. Further detail with respect to specific points raised in the Office Action is offered below.

As a preliminary matter, the Applicant notes that many of the issues and concerns related to the present case present complex and intertwining considerations. Accordingly, in the event questions remain, the Applicant requests the opportunity to pursue an interview to resolve any issues or concerns.

The Office states that the Information Disclosure Statement filed on October 11, 2005 does not include a concise statement of relevance for certain non-English language references. Please find included with this response such a statement. Also included with this response is an Information Disclosure Statement. While the Information Disclosure

Statement may increase the burden associated with examining this application, it is believed to be the only way in which Applicant may comply with its duties under 37 C.F.R. § 1.56.

The Office has raised several new matter concerns. The Applicant disagrees that the claims pose any new matter issues. However, to facilitate examination of the application, please note the Applicant has amended claim 138. These amendments are believed to fully address the new matter concerns raised by the Office. In particular, the Applicant has deleted the wording regarding “at least some of” said viable equine sperm cells. In addition, the Applicant has changed the recited success levels to “at least 87%, at least 70%, at least 53%, and at least 18% as compared to an unsorted equine artificial insemination dosage containing about the same number of sperm cells”. Support for this recitation can be found in the specification at Table 1, page 33 and accompanying text as well as Table 2, page 38 and accompanying text. These tables illustrate two trials in which equal numbers of sperm ( $25 \times 10^6$ ) were used respectively for unsorted and sorted inseminations. Pregnancy rates were 57% for  $25 \times 10^6$  unsorted sperm and 50%, 40%, 30%, and 10% for sorted sperm, as set forth in the tables. Accordingly, this data supports the recitation of claim 138 as amended.

The Office maintains an obviousness concern with respect to several combinations of references including Rens. However, Rens does not support the teachings for which the Office cites it. Specifically, the Office asserts that Rens’ teaching of orientation rates of up to 60% and sampling rates of up to 2000 sperm per sec and 15,000 sperm per sec permit the conclusion that Rens’ sorting rate is 1200 sorts per second (for sampling rates of 2000 sperm per sec) or 9000 sorts per sec (for sampling rates of 15,000 sperm per sec). It appears the Office’s methodology for reaching this conclusion is as follows:

$$(\text{sampling rate per second}) \times (\text{percent of sperm oriented}) = (\text{sorting rate per second})$$

However, this methodology is not accurate in predicting the actual sorting rate per second. In particular, the sorting rate is dependent on other factors besides percent orientation and sampling rate. These factors tend to further compromise the sorting rate and result in sorting rates that are lower than those predicted by the Office's methodology. One example of such a factor is the phenomenon of coincidence rates. Coincidence occurs when more than one cell is entrained in a single droplet, resulting in an inability of a flow cytometer to make an accurate measurement of the droplet and thus the discarding of the cells without their being sorted. Moreover, factors such as coincidence rates tend to compound as the sample rate is increased, resulting in greater complications at sample rates of e.g. 15,000 sperm per second than for e.g. 2000 sperm per second. As a result, in the absence of specific data regarding the number of sorts per second achieved by Rens, it simply cannot be inferred what Rens' true sorting rate was.

This point is evidenced by the passages of Rens cited by the Office itself. Specifically, the Office cites Rens at column 4, lines 17-18 for teaching that the elliptical nozzle of Rens is capable of sorting in excess of 60% of sperm for sorting. The Office also cites Rens at column 4, lines 29-31 for teaching that proper orientation is maintained at sample rates up to at least 15,000 sperm per second. However, the same discussion in Rens at column 4, lines 24-27 notes that the elliptical nozzle of Rens achieves only a two-fold increase in efficiency as compared to a standard conical nozzle in combination with a beveled injection needle. By way of comparison, the use of such a beveled injection needle is described in US 5,135,759 to Johnson, *see e.g.* column 3, lines 27-41 and claim 12. When Johnson used the beveled injection tip to sort intact sperm, the sorting rate was only 80-90 sperm of each type per second at a sample rate of 2500 per second, as described in Johnson at column 4, lines 14-18. Therefore, since Rens notes that its elliptical nozzle achieves only a two-fold increase in efficiency as compared to a standard conical nozzle with a beveled injection tip, it can be inferred that Rens' actual sorting rate was only on the order of 160-180 sperm per second for a sample rate of 2500 sperm per sec. This is far less than what would be predicted by the Office's methodology (2500 sperm per sec x 60% orientation = 1500 sorts per second), and is well below the sorting rates cited by the Applicant's claims.

A more detailed comparison can be made by reviewing Example 1 of Rens and comparing it to Johnson. First, note that Johnson states that approximately 15-20% of sperm are oriented when the beveled injection needle is used at a sample rate of 2500 sperm per second, *see* column 4, lines 10-15. Accordingly, using the Office's methodology, the predicted sorting rate would be 375-500 sorts per second:

$$(2500 \text{ sperm per sec}) \times (15\% \text{ orientation}) = 375 \text{ sorts per second}$$

OR

$$(2500 \text{ sperm per sec}) \times (20\% \text{ orientation}) = 500 \text{ sorts per second}$$

However, this prediction is incorrect. The data of Johnson clearly illustrate that the actual sorting rate achieved was only 80-90 sperm per second of each type, *see* column 4, lines 16-18. The discrepancy between the results predicted by the Office's methodology and the actual results is off by a factor of 4-6.

Next, note Rens at Example 1 teaches that at a sample rate of 2000 sperm per sec, the elliptical nozzle orients 52.5% of sperm. However, the question remains as to what the actual sort rate achieved was, as Rens provides no data on this point. Using the Office's methodology, the predicted sort rate for Rens should be 1050 sperm per second:

$$(2000 \text{ sperm per sec}) \times (52.5\% \text{ orientation}) = 1050 \text{ sorts per second}$$

However, Example 1 of Rens used a sample rate of 2000 sperm per sec. In order to compare Rens' data to the sample rate of 2500 sperm per sec achieved by Johnson, it is necessary to calculate what the sorting rate of Rens would be at a sample rate of 2500 sperm per second. Note that making this adjustment to Rens' sample rate should not introduce error, since Rens itself asserts at column 4, lines 29-31 that proper orientation is

maintained at sample rates of up to at least 15,000 sperm per second. Using the Office's methodology, the new predicted sorting rate is 1312 sorts per second:

$$(2500 \text{ sperm per sec}) \times (52.5\% \text{ orientation}) = 1312 \text{ sorts per second}$$

As stated previously, Rens provides no data on the actual number of sorts per second achieved. However, note that Rens in Example 1 does state that the orientation achieved with the elliptical nozzle (52.5%) is 2.3 times larger than the orientation achieved with the beveled injection tip (22.7%). Since data on actual sorts per second for a beveled injection tip at comparable sample rates is known from Johnson, *see* Johnson at column 4, lines 14-18, it may be inferred that Rens' actual sorting rate is 2.3 times Johnson's actual sorting rate, or 184-207 sorts per second:

$$(\text{Johnson: } 80 \text{ sorts per second}) \times (\text{Rens: } 2.3 \times \text{improvement}) = \text{Rens: } 184 \text{ sorts per second}$$

OR

$$(\text{Johnson: } 90 \text{ sorts per second}) \times (\text{Rens: } 2.3 \times \text{improvement}) = \text{Rens: } 207 \text{ sorts per second}$$

So, the discrepancy between the sorting rate predicted by the Office's methodology (1312 sorts per second) and the inferred actual sorting rate achieved by Rens (at best, 207 sorts per second) is off by a factor of 6-7. Moreover, the inferred sorting rate of Rens again is well below the sorting rates recited by the Applicant's claims.

Importantly, note that the above calculations are not presented in an attempt to establish what Rens' actual sorting rate was. As has been noted earlier in this and prior communications to the Office, Rens' true sorting rate cannot be accurately inferred without explicit data from Rens that establishes this fact. Rather, the above calculations are presented to illustrate the point that the true sorting rate of Rens cannot be determined simply from knowing Rens' sampling rates and orientation percentages, as the Office attempts to do. Moreover, because Rens provides no data on the actual sorting rates

achieved, it cannot be used to support an obviousness concern with regard to the Applicant's sorting rates as claimed in claim 138. Accordingly, all combinations of references cited by the Office which rely on Rens for this point similarly cannot support the same.

In addition to the sampling rate issues discussed above, Rens also does not support the teachings for which the Office cites it with regard to success levels. Specifically, Rens provides no data on success levels when sorted sperm obtained with Rens' techniques are used in artificial insemination of equines. On this point, the Office states "if Rens does not provide sufficient information to conclude that fertilization can be achieved at rates similar to the claimed rates, then it is not possible for Applicant to conclude that the method of Rens does not achieve fertilization rates comparable to that of the claimed invention". However, this position misstates who has the burden of carrying an obviousness rejection. It is the Office's responsibility to make a *prima facie* case of obviousness. MPEP § 2142. As part of making a *prima facie* case of obviousness, the Office must cite a reference or references that teach *all* the claim limitations. MPEP § 2143.03 [emphasis added]. If the Office does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. MPEP § 2142. Here, Rens teaches no information regarding success levels of the type claimed by the Applicant. Moreover, it is not the Applicant's burden to establish Rens *did not* achieve Applicant's success levels, it is the Office's burden to establish Rens *did* achieve the Applicant's success levels. If the Office cannot establish this point, it has not carried the burden of making a *prima facie* case of obviousness, and the Applicant is under no obligation to provide evidence of nonobviousness, as the Office asserts.

The Office maintains an obviousness concern with respect to a combination of references including Seidel. The Office states a declaration of George Seidel filed by Applicant under 37 C.F.R. §1.131 is not sufficient to antedate the Seidel reference. With possible exception of the requirement to establish that certain acts were carried out in the United States, the Applicant disagrees that this declaration is not sufficient to antedate the Seidel reference. However, to facilitate examination of the application, please find

attached to this response as Attachment "A" a declaration of George Seidel filed by Applicant under 37 C.F.R. §1.132. It is noted this declaration is provided pursuant to and complies with the requirements of MPEP § 716.10.

The declaration establishes that the inventor George Seidel was in possession of the subject matter of claim 138, step (g) of the present application prior to the effective filing date of the Seidel reference. Such possession is evidenced by the Declaration for Patent Application signed by the inventor George Seidel, which is dated one day prior to the effective filing date of the Seidel reference, and in which the inventor George Seidel states he had reviewed the patent application which ultimately issued as U.S. Patent No. 6,149,867. Moreover, a copy of this patent application as reviewed by the inventor George Seidel is provided, and those portions of the patent application establishing possession of the subject matter of claim 138, step (g) of the present application are identified. In this manner, it may be seen that the inventor George Seidel was in possession of the subject matter of claim 138, step (g) of the present application prior to the effective filing date of the Seidel reference.

Accordingly, the affidavit is sufficient under 37 C.F.R. §1.132 and MPEP § 716.10 to attribute to inventor George Seidel the teachings of the Seidel reference relied upon by the Office, as related to claim 138, step (g) of the present application. Because these teachings of the Seidel reference may be so attributed, such teachings may not be used in combination with the other references cited by the Office to support an obviousness rejection under 35 U.S.C. §103.

The Office has raised several nonstatutory double patenting concerns. Please find filed with this response a terminal disclaimer that the Applicant believes is sufficient to overcome these concerns.

Having addressed each of the concerns raised in the Office Action, the Applicant respectfully requests reconsideration and withdrawal of the rejections and objections to the application. Allowance of claims 138-145 is requested at the Office's earliest convenience.

Dated this 1 day of November, 2006.

Respectfully submitted,  
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